

**IN THE DRAWINGS:**

The attached 36 sheets of drawings, FIGs. 1 - 31d, replaces the original submitted drawings.

## REMARKS

### I. INTRODUCTION

With this response, formal drawings are presented to substitute the original, informal drawings, the specification is amended to correct informalities, claims 9, 10, 26 and 27 are cancelled, claims 1, 2, 7, 8, 11, 18, 19, 24, 25, 28, and 34-38 are amended to present the claims in better form, and claims 39-55 are newly added to point out various aspects of the present invention. No new matter has been introduced by these amendments. Claims 1-8, 11-25, and 28-55 are now pending in the present application.

### II. OBJECTION TO SPECIFICATION

The amendments to the specification overcome the objections raised by the Examiner in the aforementioned Office Action. The headings added in this amendment clearly delineate the proper sections of the application as required. Accordingly, Applicants request reconsideration and withdrawal of this objection.

### III. CORRECTED DRAWINGS

The attached 36 sheets of drawings, FIGs. 1 - 31d, replaces the original submitted drawings.

### IV. CLAIM REJECTIONS UNDER 35 U.S.C. §103(A)

Claims 1-38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. US2003/0208454 by Ratnoff in view of U.S. Patent Application Publication No. US2003/0110058 by Fagan. However, Applicants respectfully submit that the teachings in these references do not support the claim rejections, singly or in combination.

In particular, the claimed invention as recited in the independent claims, 1, 18 and 34-37, includes features that are neither taught nor suggested by the cited references, singly or in combination. For example, the claimed invention involves a database that, among other things, maintains event data.

Claim 1 recites this aspect as follows:

A clinical research data management system for a plurality of users comprising:  
...

a database... operable to store user data and study data, wherein the study data includes candidate data, specimen data, event data and at least one dataset, and wherein the dataset is defined using metadata.

Claim 18 recites this aspect as follows:

A clinical research data management method for a plurality of users comprising:

...

storing user data and study data in a database coupled to a computer system, wherein the study data includes candidate data, specimen data, event data and the at least one dataset

Claim 34 recites this aspect as follows:

A clinical research data management system for a plurality of users comprising:

...

a database... wherein study data includes candidate data, specimen data, event data and at least one dataset, wherein user data includes at least one role associated with each user, and wherein the role defines data access rights granted at a dataset definition level, data item definition level, or both.

Claim 35 recites this aspect as follows:

A clinical research data management system for a plurality of users comprising:

...

a database... wherein study data includes candidate data, specimen data, event data and at least one dataset, wherein user data includes at least one role associated with each user and wherein the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study.

Claim 36 recites this aspect as follows:

A clinical research data management system for a plurality of users comprising:

...

a database for storing user data and study data, wherein the study data includes candidate data, specimen data, event data and at least one dataset, and wherein the dataset is defined using metadata.

Lastly, Claim 37 recites this aspect as follows:

A clinical research data management system for administering a plurality of studies, ... comprising:

...

data access means operable to access information that resides in a system database wherein the database is operable to store user data and study data and wherein the study data includes candidate data, specimen data, event data and at least one dataset and wherein the dataset is defined using metadata.

One advantage derived from maintaining event data in the database is the ability to track events and monitor the progress of a clinical study (See, Applicants' original disclosure, e.g., at paragraphs 184-186, 190 in page 22 and at paragraphs 233-236 in page 31). To this end, event data includes status of the events.

In hindsight, it would have made sense to include event data in connection with the clinical study data management. However, only the claimed invention as recited in the above-enumerated independent claims includes this feature.

Although the Examiner suggests otherwise, Applicants do not find any mention in Ratinoff of event data (See Office Action page 5, line 11). Indeed, Ratinoff does not teach or suggest using event data or maintaining event data in the database, let alone maintaining event data as part of the study data. Instead, Ratinoff's approach builds a trusted relationship as continuum developed over time and interactions. Ratinoff's technique for developing trust, uses, for example, online interview or discussion events (See, Ratinoff at paragraphs 29 and 44; "event data" and "online discussion/interview events" are entirely different from each other). Moreover, Ratinoff's approach to gathering information for populating a database is driven by web browsing unrelated to event data and by trust that develops over time.

Fagan does not make up for Ratinoff's deficiency. Fagan discloses a clinical study period with phases during which clinical data is gathered (See, Fagan at paragraphs 19-22, 25, and 30 which mentions item 154). Collecting data during a period of time in one or more phases is different from and not suggesting collecting and maintaining event data.

Notably also, the combination of collecting data over time during regular web browsing sessions and developing a trusted relationship as a continuum using online interviews and discussions (as in Ratinoff) with collecting data during a [finite] study period in one or more phases (as in Fagan) would render Ratinoff's approach inoperable as originally envisioned. Stated differently, the proposed combination of Ratinoff and Fagan to produce the claimed invention is improper.

Hence, not only is the combination of the cited references improper, unlike the claimed invention which, among other things, uses and maintains event data, the cited references do not use or maintain event data. To support a *prima facie* case of obviousness the combined references must suggest the combination and produce the invention. In this instance the references do not support a *prima facie case* of obviousness because they do not suggest the combination and do not teach or suggest, singly or combined, each and every element of the claimed invention as

recited in claims 1, 18 and 34-37. Thus, independent claims 1, 18 and 34-37 are allowable over the cited references.

Dependent claims 2-8, 11-25 and 28-33 are allowable for the same reasons as well as other reasons. For example, claims 2 and 19 recite that the “event data includes scheduled events, unscheduled events, or both.” The Examiner alleges that, in paragraph 44, “Ratinoff teaches the claimed ... data related to scheduled (=punctual)” (See, Section 8 at page 6 of the Office Action). However, the Examiner has apparently misread the claims and misunderstood the claimed invention, as well as Ratinoff’s description. Ratinoff is not describing event data, let alone event data including scheduled or unscheduled events. Rather, Ratinoff is describing that, to build trust, online interview and interaction events need to be professional by being “punctual and well moderated” (Ratinoff paragraph 44).

In another example, claims 3 and 21 recite a system operable to “limit communication ... between users having a specific role in connection with a specific study.” The Examiner suggests that the invention recited in claims 3 and 21 is disclosed by Ratinoff at paragraph 47). However, Ratinoff discloses restricting information disseminated to users rather than when users communicate with each other.

In yet another example, claims 7 and 24 recite that “user data includes at least one role associated with each user, wherein the role is selected from the group of data monitor, enroller, data editor, study administrator, system administrator, and user administrator.” The Examiner indicates that Ratinoff teaches the claimed user data in paragraph 41. However, Ratinoff does not disclose the user data as recited in claims 7 and 21. Instead, Ratinoff discloses giving users strict control over access to their information in order to bolster their confidence in this system (See, Ratinoff paragraph 41).

In yet another example, claims 8 and 25 (and 34) recite roles associated with data access rights at a level of granularity that includes dataset definition level, data item definition level, or both. The Examiner relies on Paragraph 41 in Ratinoff in support of the proposition that Ratinoff teaches access rights at similar levels of granularity, but Applicants do not find a description of this feature in Ratinoff.

Although the foregoing examples are not exhaustive, it is clear from these examples that the cited references do not support a *prima facie* case of obviousness of claims 1-8, 11-25 and 28-38 (claims 9, 10, 26 and 27 are cancelled). Because they are neither taught nor suggested by the cited references, claims 1-8, 11-25 and 28-38 are allowable over the cited references.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the claim rejections.

V. NEWLY ADDED CLAIMS

Newly added claims 39-55 recite various aspects of the present invention. These claims recite features of the invention that are neither taught nor suggested by the cited references. Therefore, claims 39-55 are also believed to be allowable over the cited references.


VI. CONCLUSION

In view of the foregoing, Applicants believe that the application is in condition for allowance and respectfully request a Notice of Allowance of claims 1-8, 11-25 and 28-55. Should any issue remain the Examiner is kindly invited to contact the undersigned attorney for a prompt resolution thereof.

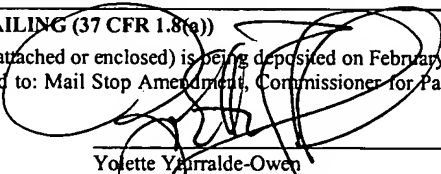
The Commissioner is authorized to charge any fee deficiency or credit any fee overpay to Deposit Account 50-2778.

Respectfully submitted,

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Date: February 17, 2005	 _____ Yolette Yarralde-Owen